DEPARTMENT OF HEALTH & HUMAN SERVICES

National Institutes of Health
National Institute of Neurological Disorders and Stroke

Office of Minority Health and Research
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SAMPLE LETTER OF AGREEMENT (LOA)

Date

Principal Investigator Name
Director, Specialized Neuroscience Research Program
Meharry Medical College
1005 D. B. Todd Boulevard
Nashville, TN 37208

Re: Competing Continuation Application for Specialized Neuroscience Research Program (SNRP) U54NSXXXXX

Dear Dr. _____

We are pleased to respond to your request to enter into another cooperative agreement with the NINDS through the submission of a competing continuation of the Specialized Neuroscience Research Program [otherwise referred to as SNRP] at the Meharry Medical College. In light of our prior agreements and collaborative interactions, we submit a memorandum to summarize the proposed nature and structure of our agreement concerning the renewal application. As you are aware, this letter of agreement sets forth the general parameters through which the NINDS, SNRP and applicant organization will collaborate if the competing application is awarded.

PURPOSE: The primary goals of the SNRPs are: (1) to help develop state-of-the-art neuroscience research programs; (2) to create more opportunities for researchers at minority institutions to establish research collaborations and professional networks with NIH and/or NSF grantees employed by research-intensive institutions; (3) to increase the role of ongoing research in maintaining a vigorous, stimulating academic and intellectual milieu that will inspire and prepare students and fellows to pursue research careers in neuroscience; (4) to provide research training opportunities for students and fellows; and (5) to provide support for pilot research needed to show the skills and abilities of investigators by obtaining the preliminary data and publications that can help ensure successful competition for traditional research project grants during the performance period of award.

OVERVIEW OF PROPOSED TYPE 2 PROJECT PERIOD APPLICATION: There are two primary components of the Type 2 application that will be evaluated equally by the Review Panel: Accomplishments during the Previous (Type 1) Project period; and Plans for the Proposed (Type 2) Project. Your application should: (1) document thoroughly the accomplishments during the initial period of award, including both scientific achievement and programmatic advancement as they relate to the goals of the Type 1 application, and (2) present detailed plans for continued scientific program development and new scientific projects.

SPECIAL REQUIREMENTS:

- To maximize the potential for success in this program, the application should show clear collaborations between the Applicant Institution and other external collaborators.

- The application should demonstrate a clearly defined administrative structure within the Institution to oversee this program.

- All applicant investigators should have completed two or more years of postdoctoral neuroscience research, and must have a full-time faculty appointment at the applicant institution.

- Collaborating investigators should have independent NIH or NSF research funding. The applicant organization should identify collaborating institutions, which may be domestic non-profit organizations, Federal or non-Federal, public or private. Because the Institution may need continuous and substantial research collaborations to achieve the objectives of this initiative, the collaborating organization should be in the U.S., its possessions, or its territories.

- **Program Director:** The principal investigator, who serves as the SNRP Director, should be an established investigator in the area of neuroscience research with a well documented record of research accomplishments and administrative skills to direct a neuroscience research program and train junior faculty. (See REVIEW CONSIDERATIONS). In the event that an Associate or Co-Director is included, the respective responsibilities and qualifications of the Associate Director or Co-Director should be clearly elucidated in the application.

MECHANISM OF SUPPORT: The administrative funding mechanism for this program is a Specialized Center Cooperative Agreement (U54), which supports research activities in which the NIH collaborates substantially in scientific and/or programmatic matters with the awardee institution. This Specialized Center Cooperative Agreement application may provide funding for (1) an administrative component which provides administrative, coordinating, planning, logistical, and other necessary support, (2) a research component, (3) a core component to augment the research capabilities of the individual research components, and (4) a training component.

The NIH seeks to support and stimulate the activities of the awardee by working as a partner. In doing so, the NIH will not assume direction, take primary responsibility, or in any other way dominate the activity. The section TERMS AND CONDITIONS contains detailed descriptions of the responsibilities, relationships, and governance of the activities supported by the SNRP.

FUNDS AVAILABLE: It is anticipated that costs will be up to $1,000,000 direct costs per year for up to five years ($1,500,000 direct costs for applications which include clinical research programs). [See http://grants1.nih.gov/grants/guide/notice-files/NOT-NS-03-020.html] Each research project may request up to $300,000 direct costs per year, including consortium agreement, for up to five years ($500,000 direct costs for clinical research programs). Although this program is provided for in the financial plans of the NINDS, an award pursuant to this agreement is contingent

upon the availability of funds for this purpose. Award and level of support depend on the receipt of an application of outstanding scientific merit as judged by the NIH dual review process.

ALLOWABLE COSTS: Allowable costs to support the administrative structure include salaries for key support personnel, equipment and supplies, and planning and coordination activities for travel of advisory committees, seminars, and consortium interactions. To enhance scientific collaborations and the success of research projects in leading to independent research funding during the performance period of the award, allowable research costs may include salaries for research staff, supplies and equipment, and travel to collaborator laboratories and scientific meetings. Finally, funds for training and career development activities such as salaries, travel, supplies, and advertising may also be included.

BACKGROUND AND SUMMARY OF PREVIOUS TYPE 1 PROJECT PERIOD

Background: The National Institutes of Health (NIH) recognizes that minority institutions are an integral component of our national biomedical research agenda, and should participate in the full range of NIH/NINDS research and research training activities to augment and strengthen our scientific and technology workforce. The purpose of the SNRP at the Meharry Medical College is to help prepare the next generation of neuroscience investigators. Beyond this, support for first-rate biomedical research programs will lead to minority medical and graduate institutions providing improved health and educational resources to minority Americans and others who have historically been served by these institutions.

TO BE FILLED OUT BY DR RUCKER

The SNRP at the MMC was funded from 2000-2005… ***(BRIEF BACKGROUND ON THE SNRP 2000-2005 PERIOD: TWO PARAGRAPHS)***

PROGRAM/RESEARCH AREAS PROPOSED FOR 2005-2009: (*INDIVIDUAL SNRP PLANS,* *examples listed below, to be no more than 5 sentences.*)

- ***Administrative Core*** *– The SNRP Director will be John Brown, Ph.D., Chairperson of the Department of Biology. The program will be housed in the Department of Biology on the Medical Sciences Campus. The SNRP Program Coordinator will be Frank Black and the SNRP administrative assistant will be Susan Miller.*

- ***Project One*** *– Jessica Brown, Ph.D., Assistant Professor, Department of Biology, will be investigating the role of alpha synuclein in Parkinson's Disease. Her collaborator will be Fred Blue, Ph.D., Professor, Department of Biology, at the University of California, San Francisco. The central hypothesis to be studied is that…*

- ***Project Two***

- ***Project Three***

- ***Scientific Core(s)*** *– A proteomics core facility will be developed to support the studies proposed in projects one and two and will be directed by Mary Black, Ph.D., Associate Professor in the Department of Biology.*

- ***Training Component (as appropriate)*** *– Support will be requested for one graduate student and one postdoctoral fellow to work in the laboratory of John Grant, Ph.D. (Project Three), Professor of Biology, an R01 supported neuroscientist.*

STOP

KEY COMPONENTS IN THE APPLICATION

Organizational Outline: See APPLICATION PROCEDURES below for a detailed description of each of the following sections within the outline. Follow the specific order indicated in the section PREPARING YOUR APPLICATION below.

I. Previous Type 1 Project Period
   a. Programmatic Accomplishments
   b. Scientific Accomplishments

II. Proposed Type 2 Project Period
   a. Background and Objectives
   b. Scientific and Administrative Leadership
   c. Administrative Structure
   d. Faculty Recruitment
   e. Research Projects
   f. Core Component
   g. Training Component (if applicable)

The following provides a description of key components that should be considered for inclusion in the application.

Scientific and Administrative Leadership

The applicant organization must select and appoint a SNRP Director who has had experience with neuroscience research funding and research training. In special circumstances where a Co-Director structure has demonstrated to be most effective in administering such a program, this framework and the qualifications of the Co-Director should be well justified.

Administrative Structure

- There should be clear evidence of an established administrative structure, delineating the roles for program management, the Scientific Advisory Committee (SAC), and the Program Advisory Committee (PAC), to foster interactions among investigators and scientific collaborators that will accelerate the pace of research accomplishments.

- There should be a clear and concise description of the chain of responsibility for the SNRP Director in decision making and administration, beginning at the level of the institution's President and including all key staff (e.g., Dean, Department Chair, PAC, Sponsored Programs Administrator). Description of plans for day-to-day administration of the program, including program coordination, planning, and evaluation should be included. Description of the proposed relationship between this program and other existing programs at the Institution must be

provided. There should be information provided on how this initiative will strengthen the research infrastructure at the Institution.

- The Administrative Core will contain sufficient staff to administer program functions including coordination of meetings for the Scientific and Program Advisory Committees; preparation of minutes; organization of courses, seminars, and other scientific gatherings; subcontracts with collaborating institutions; maintaining membership rosters and committee lists; arranging for mock reviews of proposals and manuscripts; and other secretarial, administrative and logistical support as needed by the program.

- The Scientific Advisory Committee (SAC) has a primary duty to conduct, implement and complete the approved research plan proposed in the application. The SAC should consist of the SNRP Director, project investigators, collaborators and must include scientific advisors with expertise relevant to the SNRP projects. Annually, the SAC should meet in conjunction with the Program Advisory Committee meeting to evaluate overall scientific progress. In addition, the SAC should meet, as often as required either in person, electronically, via teleconference or videoconference, to ensure compliance with the Terms and Conditions of Award, to ensure progress and productivity in the research projects, to ensure the completion of manuscripts and grant proposals, and to make recommendations for mid-course corrections as needed. Beyond the above, project investigators should provide SAC members with draft manuscripts and grant proposals at least one week before each meeting. SAC members should provide written comments on all manuscripts and grant proposals to the project investigators. Scientific progress should be documented in the form of written reports submitted quarterly to the PAC and the NIH. The composition of the SAC should be evaluated annually and amended or revised as necessary. Other internal planning and evaluation methods for assuring progress of the program should be described such as review of manuscripts and grant proposals by other colleagues.

- The Program Advisory Committee (PAC) should be established during the pre-application phase. Membership should include national neuroscience research experts and at least one individual with experience in administering sponsored programs in an academic setting. The chair of the Committee will be elected by and from the members of the PAC. The PAC will provide independent advice and guidance to the SNRP Director and Administration, similar to a NIH Study Section. The PAC must meet at least annually to evaluate progress in the administration and management of the SNRP, to review and assess overall research performance towards intermediate and long term outcome goals in the program and individual projects, revise and/or establish reasonable performance measures during the annual evaluation of the program, and assist the administration and SNRP Director in providing innovative solutions to scientific and administrative barriers in the program. The PAC will evaluate the following:

    - The performance of the SNRP Director, the SAC, the Institution, and Project Investigators (including recommendations on actions to be taken), specifically with respect to the negotiated Terms and Conditions outlined in the Notice of Grant Award;

    - Additional research endeavors within the scope of the approved research and negotiated budgets;

- Proposed research projects prior to submission to NIH for competitive peer review; and

- The recruitment of new scientific and technical staff to the program, including an assessment of qualifications to conduct high quality research, and the potential for collaborations.

The PAC will also be comprised of non-voting (ex officio) members, including any NIH collaborators and program staff, and one Executive Secretary, identified from the SNRP staff. The Executive Secretary, other ex officio members, and ad hoc consultants and investigators may not vote.

The Executive Secretary will be responsible for preparing the minutes from each meeting within two weeks of the PAC meeting. Within 30 days of the PAC meeting, the Chairperson of the PAC will forward a copy of the final recommendations (signed/approved by the PAC Chairperson) to the other members of the PAC, the SNRP Director and the NIH. The SNRP Director should review the PAC recommendations with senior officials at the Institution and provide a plan of implementation (signed/approved by the applicant organization) to accept or reject the recommendations of the PAC. If a recommendation is rejected, the SNRP Director must provide a detailed justification for not implementing the recommendation. The plan of implementation should be sent to the PAC and the NIH within 60 days of the PAC meeting. The NIH must review and approve the plan prior to implementation. (See Terms and Conditions Section). Approved implementation plans will be incorporated into the Terms and Conditions of Award.

Institutional Commitment

- Senior officials within the applicant organization must address the authority of the SNRP Director to manage research personnel with respect to hiring, promotion, research release time, and other matters pertaining to the scientific success and expansion of the research program. This should include evidence of the availability and management of technical resources and facilities for the long-term support of the program. Letters of support and commitment from senior officials (e.g., President, Provost or Dean) at the applicant organization should outline the commitment for resources and facilities (e.g. space, FTEs, and start-up packages for the recruitment of additional faculty) to sustain and support the program throughout the period of funding as well as beyond the performance period of this award.

Resources and Environment

- Features of the institutional environment that are relevant to overall effectiveness of the research program should be briefly described. As appropriate, available resources (e.g., laboratory facilities, geographic distributions of space and personnel) and collaborative resources at participating institutions should be included as part of the application.

- Identification and outline of plans for procurement (e.g., grants management, administrative, and technical) to ensure the timely ordering of research supplies and other essential resources.

- Evidence of existing research infrastructure to support the program. Previous (past five years) and current research support for neuroscience research should be described. The existing research infrastructure and needed enhancements should be delineated. Examples of research infrastructure include procurement procedures, office of sponsored programs and animal care facilities.

Research Program

The research program should include up to three highly qualified applicant investigators proposing collaborative research projects suited to their neuroscience research expertise and those of the collaborating investigator. These projects may be the initiation of exploratory research projects related to the goals of the program and should be described in the application. Collaborative projects must document the nature and scope of the collaboration with NIH/NSF grantees. Project investigators must devote a minimum of 50 percent effort to their research projects and mentor/collaborators must devote a minimum of 10 percent effort to the project. The research plan may also include current project investigators and other funded investigators seeking funding to develop new projects. For these cases, a maximum allowable percent effort will be 20 percent. Core units that provide common support activities, such as administrative or scientific (e.g. biochemical, pathological, or genetic analyses) activities may also be included if justified.

Training Program

A limited training component may be added at this time to provide research training and career development activities to undergraduate, graduate and medical students, and postdoctoral fellows given the adequacy of the training environment (e.g. independently funded mentor/trainers, academic caliber of the trainees, adequacy of the resources in the training environment, research and training productivity).

PROPOSED TERMS AND CONDITIONS

The following Terms of Award are in addition to, and not in lieu of, otherwise applicable OMB administrative guidelines, HHS Grant Administration Regulations at 45 CFR Part 74 and 92, and other HHS, PHS, and NIH grant administration policies. Cooperative Agreements are subject to the administrative requirements outlined in pertinent OMB, HHS, PHS, and NIH guidelines, with particular emphasis on HHS regulations at 42 CFR Part 52 and 45 CFR Part 74. Indirect costs are calculated and awarded for cooperative agreement awards the same as for grants.

1. The Awardee Institution (AI) Rights and Responsibilities:

- The AI has primary authority and responsibility to define the scientific objectives and approaches, and to plan, conduct, analyze, and publish results, interpretations, and conclusions of the studies;

- The AI has the primary responsibility for establishing effective and substantial research collaborations with NIH and/or NSF grantees. The scope and nature of research on common protocols should be adequately documented and should ensure participation, collaboration, and sharing of methods and data among collaborating organizations;

- The AI has the primary responsibility for establishing a SAC. The committee will have the responsibility for directing and monitoring the progress of the research projects and providing written comments on all manuscripts and grant applications. Beyond this, the committee should develop opportunities for information exchange, seminar presentations, and research training opportunities for students, residents, and fellows;

- The AI has the primary responsibility for establishing a PAC of distinguished senior scientists. The PAC is expected to contribute to the scientific and programmatic development of the application. Annually, the committee will assess the productivity of the program, make recommendations for the future direction of the SNRP initiative, and provide advice and guidance about personnel matters and the allocation of resources to individual projects and researchers; and

- The AI will retain custody of and primary rights to the data and intellectual property developed under the award, subject to current government policies regarding rights of access as consistent with current HHS, PHS, and NIH policies. The NIH reserves the right to negotiate additional terms and conditions with the awardee institution based on recommendations from the Initial Review Group, and the National Advisory Councils for the NINDS and other funding partners.

2. NIH Staff Responsibilities:

The NIH will have substantial scientific/programmatic involvement during the award performance period by contributing to planning and assessment activities, providing technical assistance, and by advice and coordination beyond normal program stewardship for grants. Scientific collaborators are identified in the INQUIRIES section.

- The NINDS-OMHR and other NIH Scientific Collaborators will have primary responsibility for stewardship of the award and overall responsibility for monitoring the conduct, progress, and fiscal management of the research program;

- The NINDS-OMHR and other NIH Collaborators will help shape a comprehensive framework for the development of the program, and provide technical advice and expertise regarding scientific direction and program management;

- The NINDS-OMHR and other NIH Collaborators will help the applicant institution and SNRP Director establish reasonable time lines to achieve the developmental goals of the program. The NIH will facilitate interactions between the AI and collaborating investigators;

- The NINDS-OMHR and other NIH Collaborators reserve the authority to recommend reductions in budget, withhold support, suspend and/or terminate the award if technical performance falls below acceptable standards for quality and timeliness;

- The NINDS-OMHR and other NIH Collaborators will actively participate as non-voting members in all meetings of the PAC during the performance period of the award;

- The NINDS-OMHR and other NIH Collaborators will have the authority to recommend additional research endeavors within the approved research and negotiated budgets; and,

- The NINDS-OMHR and other NIH Collaborators reserves the right to include selected extramural and intramural staff as consultants/experts on scientific issues during the performance period of the award.

3. Arbitration

Any disagreement that may arise on scientific or programmatic matters (within the scope of the award) between award recipients and the NIH may be brought to arbitration. An arbitration panel will be composed of three members - one selected by the Principal Investigator, a second member selected by the NIH staff, and a third member selected by the two prior selected members. The decision of the arbitration panel, by majority vote, will be binding. The process to resolve programmatic differences described above in no way affects the rights of a recipient of a cooperative agreement assistance grant to appeal an adverse determination in accordance with PHS regulations at 42 CFR Part 50, Subpart D, and HHS regulations at 45 CFR Part 16.

4. Noncompliance with terms and conditions:

Noncompliance with the terms and conditions of this award may result in a reduction of the recommended budget, withholding of support, suspension, or termination of award.

APPLICATION PROCEDURES

You have requested that we provide specific guidance on how to submit an application for this cooperative agreement. We have listed below some suggestions on how to construct an application that will meet the guidelines for a U54 and also the specific needs of the proposed program.

As in any research application, the research grant application form PHS 398 (rev. 5/01) is to be used in applying for this grant. This form is available at your institutional office of sponsored research and may also be obtained from the Division of Extramural Outreach and Information Resources, National Institutes of Health, 6701 Rockledge Drive, MSC 7910, Bethesda, MD 20892-7910; telephone (301) 435-0714; Email: grantsinfo@nih.gov; and from the NIH program administrator listed under INQUIRIES. It may also be downloaded from the Internet at http://grants.nih.gov/grants/forms.htm.

PREPARING YOUR APPLICATION

Read all of the instructions thoroughly prior to preparing your application. See instructions at: http://grants1.nih.gov/grants/funding/phs398/section_1.html

Some important features of the application include:

1. Face Page (use Form Page 1):
    - Item 1: provide a title that is specifically descriptive to your program.

- Item 2: it would be helpful if you entered "U54" to the right of the title.
- Item 3d, 12 and 13: include valid e-mail addresses.
- Item 15: in signing the application face page, the duly authorized representative of the applicant organization certifies that the applicant organization will comply with all applicable assurances and certifications referenced in the application.

2. Description, Performance Site(s) and Key Personnel (use Form Page 2):
   - Key Personnel: List only those individuals who will contribute in a substantive way to the scientific development or execution of the project, whether or not salaries are requested.

Note: The name of the principal investigator/program director must be provided at the top of each printed page and each continuation page.

3. Research Grant Table of Contents (use Form Page 3):
   - Provide a page number for each category listed on the Table of Contents. The Table of Contents may include the following:

     Face Page
     Description, Performance Sites and Key Personnel
     Table of Contents
     Detailed Budget for Initial Budget Period:
     - Administrative Core
     - Research Project(s)
     - Scientific Core(s)
     - Training Component (if applicable)

     Budget for Entire Proposed Period of Support:
     - Administrative Core
     - Research Project(s)
     - Scientific Core(s)
     - Training Component (if applicable)

     Budgets Pertaining to Consortium/Contractual Arrangements
     Biographical Sketch of Principal Investigator (not to exceed two pages)
     Biographical Sketches of Key Professional Personnel (not to exceed two pages each for each individual)
     Biographical Sketches of External Advisors (not to exceed two pages each)
     Other Support of Principal Investigator, and Key Personnel
     Resources
     Letter of Institutional Commitment

     Research Plan
     - Specific Aims
     - Background and Objectives
     - Report on Previous Type 1 Project Period ***%50 of the Score**
     - Scientific and Administrative Leadership
     - Administrative Structure
     - Faculty Recruitment
     - Research Projects
     - Core Component
     - Training Component (if applicable)
     - Consortium/Contractual Arrangements

- Intellectual Property (if appropriate)
- Human Subjects (if applicable)
  - Protection of Human Subjects
  - Inclusion of Women
  - Inclusion of Minorities
  - Inclusion of Children
  - Data and Safety Monitoring Plan
- Vertebrate Animals (if applicable)
- Literature Cited
- Consortium/Contractual Arrangements
- Letters of Support (e.g., Consultants)
- Checklist
- Appendix (if applicable)

DETAILED BUDGET FOR INITIAL BUDGET PERIOD (DIRECT COSTS ONLY): Use Form Page 4 of the Form PHS 398 application kit. Each item listed in each prepared budget must be clearly justified using Form Page 5's. Using separate Form Page 4's, break out the budget using the following headings:

a. Administrative Core - Include all the costs for salaries of administrative personnel, including the SNRP Director and Co-Director (if applicable); travel and per diem for administrative personnel and outside advisors; and equipment and supplies to support administrative needs. All Personnel categories must be filled in (i.e., name, role on project, type of appointment/months, % effort on project, institutional base salary, salary requested, fringe benefits and totals). Whether or not costs are involved, provide the names and organizational affiliations of all consultants, and describe in detail their services to be performed (i.e., the number of days of anticipated consultation, the expected rate of compensation, travel, per diem, and other related costs).

b. Research Projects - Use separate page 4s for each project. If there is more than one project, at the top of each page number projects consecutively (e.g., Project 1, Project 2, etc.). Include all costs for salaries of scientific personnel, travel and per diem for all project personnel to collaborating laboratory and scientific meetings, as appropriate, and supplies and equipment necessary to carryout the proposed project. Include a separate detailed budget page for costs related to the consortium agreement, including facilities and administrative (indirect) costs. All Personnel categories must be filled in (i.e., name, role on project, type of appointment/months, % effort on project, institutional base salary, salary requested, fringe benefits and totals). Whether or not costs are involved, provide the names and organizational affiliations of all consultants, and describe in detail their services to be performed (i.e., the number of days of anticipated consultation, the expected rate of compensation, travel, per diem, and other related costs).

c. Scientific Cores – Use separate page 4s for each core. If there is more than one core, at the top of each page number the cores consecutively (e.g., Core 1, Core 2, etc.). Include all costs for salaries of scientific personnel, supplies and equipment necessary to support the core facility. All Personnel categories must be filled in (i.e., name, role on project, type of appointment/months, % effort on project, institutional base salary, salary requested, fringe benefits and totals). Whether or not costs are involved, provide the names and organizational affiliations of all consultants, and describe in detail their

services to be performed (i.e., the number of days of anticipated consultation, the expected rate of compensation, travel, per diem, and other related costs).

d. Training Component (if applicable) – Include all costs for student salaries, travel, supplies for research activities, advertising and recruitment. All Personnel categories must be filled in (i.e., name, role on project, type of appointment/months, % effort on project, institutional base salary, salary requested, fringe benefits and totals). Whether or not costs are involved, provide the names and organizational affiliations of all consultants, and describe in detail their services to be performed (i.e., the number of days of anticipated consultation, the expected rate of compensation, travel, per diem, and other related costs).

Effective March 3, 2004, the Executive Level I salary cap level increased to $175,700. The maximum amount of allowable support for a graduate student is equal to the zero level of NRSA stipend level which is in effect at the time the award.

BUDGET FOR ENTIRE PROPOSED PERIOD OF SUPPORT: Using Form Page 5 of the Form PHS 398, follow the instructions in the Form PHS 398 application kit.

BIOGRAPHICAL SKETCH OF ALL KEY PERSONNEL INCLUDING CONSULTANTS, AND SCIENTIFIC AND PROGRAM ADVISORY COMMITTEE MEMBERS (not to exceed two pages for each individual): Use the Biographical Sketch format Page in the Form PHS 398 and follow the instructions in the application kit.

OTHER SUPPORT: This information is required for all applications that are to receive grant awards; however, NINDS will request complete and up to date "Other Support" information from applicants at an appropriate time after peer review. See Form PHS 398 application kit for details.

RESOURCES: Follow the sample format and instructions on the Resources Format Page provided in the Form PHS 398 application kit. If there are multiple performance sites, then resources available at each site should be described.

LETTERS OF COMMITMENT: The institutional leadership (e.g., Dean, President) should include a detailed statement of their long-term commitment by noting the specific resources that will be dedicated to each stage of this planning effort. These resources could be in the form of protected time (i.e., release time) for faculty to focus on the objectives of this grant, new faculty appointments with competitive recruitment packages (salary, space and start-up commitments), purchase of sophisticated equipment for critical infrastructure needs, and discretionary resources that will be made available to the Principal Investigator to achieve objectives that will build a stronger institutional culture dedicated to this effort.

Collaborators, consultants and advisors should also submit letters outlining their commitment to the development of neuroscience research at the Meharry Medical College, to the individual research projects, and/or to the training program, as appropriate.

RESEARCH PLAN

SPECIFIC AIMS

PREVIOUS TYPE 1 PROJECT PERIOD

Programmatic Accomplishments: The application should document the programmatic accomplishments that were achieved in the Previous Type 1 Project Period. For example this should include descriptions of infrastructure improvements, technology transfer, scientific cores, advisory council functions, etc.

Scientific Accomplishments: The scientific accomplishments from the Type 1 award (e.g. should be described. These include publications, grants, etc., and any other unanticipated advances that resulted from the initial award.

If goals were not achieved in the Type 1 award, describe plans for addressing these deficiencies in the future.

PROPOSED TYPE 2 PROJECT PERIOD

Background and Objectives: The application should outline the long-term goals and vision for the program. The Principal Investigator should list the specific interim and final objectives that are expected to be achieved in chronological order with the expected times (e.g., months, years) for completion during the period requested in this grant. These objectives should include scientific and career development benchmarks for each of the project investigators as well as programmatic objectives for the SNRP Director and the institutional leadership.

Scientific and Administrative Leadership: Briefly describe the qualifications and experience of the SNRP Director in providing leadership and cohesion for this effort. Also, if there are other mid-level leaders who will play a significant role in determining the success of this program, provide the same information for them.

Administrative Structure: Describe the leadership and specific functions of the administrative core to provide the necessary regular day-to-day oversight, coordination, support, and logistics services needed to make this partnership function effectively. This might include organizing meetings, workshops, courses, seminars, and retreats; preparation of minutes; subcontracts with collaborating institutions; maintaining membership rosters and committee lists; arranging for mock reviews of proposals and manuscripts; and other secretarial, administrative and logistical support as needed by the program.

Describe the expertise of the individual members of the SAC and PAC and the rationale for their selection. Describe the role of the SAC in scientific oversight and guidance as well as manuscript and grant proposal review to enhance the research accomplishments of the program. Comment on how the PAC will effectively evaluate this program relative to its research and programmatic objectives.

Faculty Recruitment: Describe specific faculty recruitment(s). Depending upon the long-term goals of the program, recruitment of faculty or additional mentored research of existing faculty may be necessary to build the research capability at the Institution. For any planned faculty recruitment, please provide a letter of commitment from senior Institutional leadership to these hires. The following information should be provided for faculty recruitment:

Individuals who are known:

a) Provide the biographical sketch of the individual;
b) Describe how the individual fulfills the objectives of the program;
c) Describe how the position will provide the necessary stability (e.g. tenure track) and resources (e.g. space) to promote success;
d) Describe the location of the individual at the Institution and how this location will best achieve the objectives of the program; and
e) Timeline for recruitment.

For anticipated recruitments:

- Describe the number and expertise of the individuals to be recruited to strengthen research capabilities in those areas needed to fulfill the objectives of the program and the timeframe for the recruitment. Describe the recruitment package to be provided by the Institution.

Research Projects: For each research project, submit a research plan, beginning with the title page, followed by an abstract page (use form page 2 of the PHS 398 application kit). Subsequent pages should describe the research plan using the standard subheadings for a research plan of an investigator-initiated R01 grant application. In addition, include details regarding the proposed interactions between the project investigator and his/her collaborator (e.g. frequency and purpose of interaction; technique transfer; manuscript and grant reviews). Also, include a timeline for the proposed research, including anticipated manuscript and grant proposal submission dates.

For interim support of previously supported project investigators, provide a description of the plan for the revision and re-submission of R01 applications, including a plan for collecting additional data, if necessary, mechanisms for the pre-review of proposals, and a timeline for re-submission.

Core Component: For each core, justify the need for the core in support of the research projects proposed. Describe the plans for the use of the core and the qualifications of the core leader.

Training Component (if applicable): Describe the objectives, design and direction of the training plan. If applicable, describe the past training record of both the program and the designated preceptors. Outline the commitment and availability of the participating faculty, the institutional commitment, the availability of research support, the quality of research facilities and the training environment. Describe the applicant pool and the selection process. Describe plans to evaluate the success of the program. Outline plans for minority recruitment and report on recruitment in the previous award period, if applicable. Provide plans for education in the responsible conduct of research for all students.

Intellectual Property: See instructions in the Form PHS 398 application kit.

Checklist: Address all items on the Checklist Form Page. For each grant year, provide the amount of base and the current F&A cost rate established and calculate a total. Under the "Explanation" section, and for each budget year, list the F&A exclusion items separately by category and their associated costs (e.g., equipment, $10,000; tuition remission $1,200; patient care, $20,000, etc.). A separate Checklist Form Page should be completed for each consortium/contractual arrangement.

Mailing Address for Application

Submit a signed, typewritten original of the application, including the Checklist, and three signed photocopies, in one package to:

Center For Scientific Review
National Institutes of Health
Suite 1040
6701 Rockledge Drive, MSC 7710
Bethesda, MD 20892-7710 (USPS for express or regular mail)
Bethesda, MD 20817 (express mail or overnight courier service)
(see: http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-03-040.html)

At the time of submission, two additional copies of the application should be sent to:

Dr. Alan Willard
Scientific Review Branch
National Institute of Neurological Disorders and Stroke
Neuroscience Center, Room 3208
6001 Executive Boulevard
Bethesda, MD 20892-9529
Rockville, MD 20852 (For Express/Courier Service)

REVIEW CONSIDERATIONS: Upon receipt, the application will be reviewed for completeness by the Center for Scientific Review and for responsiveness by NINDS staff. An application that is incomplete and/or non-responsive to this memorandum, or exceeds the maximum first year direct cost limit, excluding indirect costs for consortium budgets, will be returned to the applicant without further consideration. A Special Emphasis Panel (SEP) convened by the NINDS will determine the scientific merit of the application.

REVIEW CRITERIA: The proposed program is quite broad in scope. Accordingly, the review criteria are consistent with those for traditional research project grants. Beyond this, reviewers must exercise considerable flexibility in determining the merits of the research application to strengthen research capabilities amongst the collaborating institutions and to enhance training and career development opportunities for neuroscience students, fellows and faculty.

The Specialized Center Grant Cooperative Agreements (U54s) differ from a program project grant (P01 or P50) in that it is usually developed in response to an announcement of the programmatic needs of an Institute or Division and subsequently is managed at the highest administrative levels as a high-priority activity. Specialized Centers may also serve as regional or national resources for special research purposes, with funding component (NINDS) staff helping to identify priority needs.

The review of the U54 application is based not only on the traditional review criteria for research projects, but also include special requirements:

1. The application must have scientific merit, but, unlike a traditional research grant application or program project grant, it should be evaluated in the context of the developmental goals of the award. Unlike program project grants, U54s need not have a central scientific thematic focus.

2. Many of the project investigators are at the beginning of their research careers and reviewers should consider the feasibility and promise for these investigators to gain scientific independence.

3. Reviewers should evaluate the applicants' potential for productive collaborative research and the overall potential of the award for enriching the academic and intellectual milieu at the applicant institution.

The initial review group will convene as a Special Emphasis Panel and proceed with a site visit to the applicant organization. Prior to the visit, reviewers will prepare preliminary reviews of the scientific and technical merits of the application, with the goal of conducting interviews of the U54 principal investigator, participating project investigators, and institutional representatives.

THE SITE VISIT. The initial review group will first evaluate the individual research projects and core components using the criteria outlined below. They will then assess the overall program, considering the interrelationships and synergies among the various components. The site visitors will have an opportunity to interact with the applicants and to tour the facilities.

I. OVERALL EVALUATION

Evaluation of Previous Project Period: For competing continuation applications, this section should address the applicants' progress towards the following goals:

- Scientific accomplishments (e.g. publications, presentations, grant applications, etc.);
- Programmatic accomplishments (e.g. infrastructure improvements, technique transfer, recruitment, administrative improvements, etc.);
- Institutional support (e.g. construction/renovations; FTEs, space allocation, etc.);
- Unanticipated advancements (e.g. summer student research programs; endowed chairs, etc.);
- Methods for improvement upon previous project period;

Evaluation of the Proposed Program: This section should address the following aspects:

- The scientific merit of the program as a whole, as well as that of individual projects;
- The likelihood that applicant investigators will produce the publications and preliminary data needed to be competitive for a traditional research grant during the performance period of the award;
- The nature and extent of research collaborations. Assess whether or not the current and/or proposed scientific collaborations strengthen the research capabilities of personnel at the awardee institution;
- The adequacy of existing facilities and plans for their further development;

- The quality of the scientific and intellectual milieu for conducting the research, and plans for further development;
- The plans for career development of students and fellows in neuroscience research and other neuroscience-related health professions;
- The feasibility of the planned research program within the time and budget requested; and

Administrative Adequacy: Evaluate:

- The scientific and administrative leadership and ability of the principal investigator/program director, and his/her commitment to guide the development of the program to its fullest potential;
- The plans for oversight and monitoring of progress during the performance period of the award, and the criteria to be used to measure progress;
- The institutional (administrative, departmental and interdepartmental) support for the proposed program, including the commitment of resources and the guarantee of faculty time available for research;

Overall Budget: The SRA will prepare this section with input from the committee.

Animal Welfare, Human Subjects, and Gender, Minority and Childrens' Participation: Adequacy of the proposed means for protecting against or minimizing potential adverse effects upon humans, animals, and/or the environment. When human subjects are involved, the adequacy of plans to include women, minorities and children in the study. See attached information sheets for additional information regarding these issues.

II. REVIEWS OF INDIVIDUAL SUBPROJECTS AND CORES

Review Criteria for New Investigator Projects:

An important program goal of the SNRP is to provide funding support for new investigators to develop the necessary preliminary data and publications to successfully compete for independent research funding during the period of award. Typically, new investigators are less experienced in the preparation of applications and in the expression of their research plans. As such, the reviewers should base their evaluations on the feasibility, promise and potential of the new investigator, and not on actual accomplishments. All applicants should be evaluated in a manner appropriate for their stage of career. Beyond these considerations, reviewers may also assess the merits of the projects using the standard review criteria:

(1) **Significance**

Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

(2) **Approach**

Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

(3) **Innovation**

Does the project employ novel concepts, approaches or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

(4) **Investigator**

Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)?

(5) **Environment**

Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

Review Criteria for Continued Scientific Projects (From Previous Type 1 Project Period):

- Is there an adequate plan for the revision and re-submission of the R01 application?

Review Criteria for Developmental Research Projects for Senior Faculty:

The reviewers will evaluate these projects using the standard NIH review criteria: (1) Significance; (2) Approach; (3) Innovation; (4) Investigator; and (5) Environment (detailed above).

Review Criteria for Cores:

1. Utility of the core to the program; each core should provide essential facilities or service for two or more projects judged to have substantial scientific merit;
2. Quality of the facilities or services provided by this core (including procedures, techniques, and quality control) and criteria for prioritization of usage;
3. Qualifications, experience, and commitment of the personnel involved in the core.

Review Criteria for Training Component:

1. Is the design of the training program adequate to achieve the stated objectives? What is the past training record of both the program and the designated preceptors (if applicable)?

2. Are the qualifications and commitment of the participating faculty, institutional commitment, availability of research support, quality of research facilities and training environment adequate?

3. What is the quality and size of the applicant pool? What are the plans to evaluate the success of the program?

4. Is the plan to recruit and retain underrepresented minorities in the training program adequate?

5. If applicable, has the program been successful in recruiting and retaining underrepresented minorities?

6. Is the plan for training in the responsible conduct of research appropriate?

Budget: Appropriateness of the proposed budget and timetable in relation to the scope of the proposed research.

Overlap: Any apparent overlap with other active or pending grants to alert NINDS staff to review the total funding situation.

Animal Welfare, Human Subjects, and Gender and Minority Participation

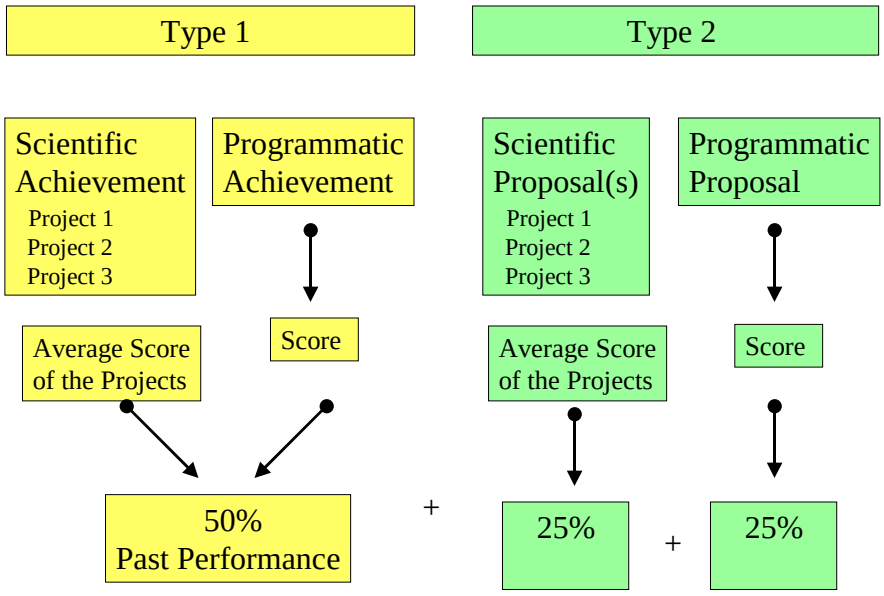
ADDITIONAL REVIEW CRITERIA: In addition to the above criteria, your application will also be reviewed with respect to the following:

PROTECTIONS: The adequacy of the proposed protection for humans, animals, or the environment, to the extent they may be adversely affected by the project proposed in the application.

INCLUSION: The adequacy of plans to include subjects from both genders, all racial and ethnic groups (and subgroups), and children as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated. (See Inclusion Criteria included in the section on Federal Citations, below)

DATA SHARING: The adequacy of the proposed plan to share data.

SCORING



AWARD CRITERIA: Applications submitted in response to a PA will compete for available funds with all other recommended applications. The following will be considered in making funding decisions:

- Scientific merit of the proposed project as determined by peer review
- Availability of funds
- Relevance to program priorities

NIH Scientific Collaborators: We welcome the opportunity to clarify any issues or questions. The staff at the NINDS who will have programmatic responsibility for this cooperative agreement is listed below:

Dr. David A. Jett
Program Director
Office of Minority Health and Research
National Institute of Neurological Disorders and Stroke
Neuroscience Center, Suite 2149
6001 Executive Boulevard
Bethesda, MD 20892-9535
Telephone: (301) 496-6035
FAX: (301) 594-5929
Email: dj140o@nih.gov

For information on budget and fiscal matters, contact:

Grants Management Branch
National Institute of Neurological Disorders and Stroke
Neuroscience Center, Room 3264

6001 Executive Boulevard
Bethesda, MD 20892
Telephone: (301) 496-3938
FAX: (301) 451-5635

REQUIRED FEDERAL CITATIONS

HUMAN SUBJECTS PROTECTION: Federal regulations (45CFR46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.
http://www.ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm

MONITORING PLAN AND DATA SAFETY AND MONITORING BOARD: Research components involving Phase I and II clinical trials must include provisions for assessment of patient eligibility and status, rigorous data management, quality assurance, and auditing procedures. In addition, it is NIH policy that all clinical trials require data and safety monitoring, with the method and degree of monitoring being commensurate with the risks (NIH Policy for Data Safety and Monitoring, NIH Guide for Grants and Contracts, June 12, 1998: http://grants.nih.gov/grants/guide/notice-files/not98-084.html).

INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH: It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing clinical research should read the AMENDMENT "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research - Amended, October, 2001," published in the NIH Guide for Grants and Contracts on October 9, 2001 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html); a complete copy of the updated Guidelines are available at http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm. The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the new PHS Form 398; and updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS: The NIH maintains a policy that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include

them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the inclusion of children as participants in research involving human subjects that is available at http://grants.nih.gov/grants/funding/children/children.htm.

REQUIRED EDUCATION ON THE PROTECTION OF HUMAN SUBJECT PARTICIPANTS: NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for research involving human subjects. You will find this policy announcement in the NIH Guide for Grants and Contracts Announcement, dated June 5, 2000, at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html.

HUMAN EMBRYONIC STEM CELLS (hESC): Criteria for federal funding of research on hESCs can be found at http://grants.nih.gov/grants/stem_cells.htm and at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html. Only research using hESC lines that are registered in the NIH Human Embryonic Stem Cell Registry will be eligible for Federal funding (see http://escr.nih.gov). It is the responsibility of the applicant to provide the official NIH identifier(s)for the hESC line(s)to be used in the proposed research. Applications that do not provide this information will be returned without review.

PUBLIC ACCESS TO RESEARCH DATA THROUGH THE FREEDOM OF INFORMATION ACT: The Office of Management and Budget (OMB) Circular A-110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm.

Applicants may wish to place data collected under this PA in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

STANDARDS FOR PRIVACY OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION: The Department of Health and Human Services (DHHS) issued final modification to the "Standards for Privacy of Individually Identifiable Health Information", the "Privacy Rule," on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information, and is administered and enforced by the DHHS Office for Civil Rights (OCR). Those who must comply with the Privacy Rule (classified under the Rule as "covered entities") must do so by April 14, 2003 (with the exception of small health plans which have an extra year to comply).

Decisions about applicability and implementation of the Privacy Rule reside with the researcher and his/her institution. The OCR website (http://www.hhs.gov/ocr/) provides information on the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, funding, and progress monitoring of grants, cooperative agreements, and research contracts can be found at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html.

URLs IN NIH GRANT APPLICATIONS OR APPENDICES: All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Furthermore, we caution reviewers that their anonymity may be compromised when they directly access an Internet site.

HEALTHY PEOPLE 2010: The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This PA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at http://www.health.gov/healthypeople.

AUTHORITY AND REGULATIONS: This program is described in the Catalog of Federal Domestic Assistance Nos. 93.853. Awards are made under authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and administered under NIH grants policies described at http://grants.nih.gov/grants/policy/policy.htm and Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

We look forward to working with you on this important project and welcome the opportunity to continue our discussions of your application for a cooperative agreement.

Sincerely,

David A. Jett, Ph.D.
Program Director
Office of Minority Health and Research

cc:
Dr. Audrey Penn
Dr. Robert Finkelstein
Chief, Grants Management Officer